



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/263,626 03/05/99 MOORE

P PF466

EXAMINER

HM22/1001

A ANDERS BROOKES
HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE MD 20850

O HARA, E

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

10/01/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/263,626

Applicant(s)

Moore et al.

Examiner

Eileen O'Hara

Group Art Unit

1646



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-24 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-24 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1646

DETAILED ACTION

1. Claims 1-24 are pending in the instant application.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-10, 14, 15 and 22, drawn to polynucleotides, vectors, host cells and a recombinant method of producing protein, classified in class 536, subclass 23.5, class 435, subclasses 320.1, 252.3 and 69.1.
 - II. Claims 11, 12 and 16, drawn to polypeptides, classified in class 530, subclass 350.
 - III. Claim 13, drawn to an antibody, classified in class 530, subclass 388.22.
 - IV. Claim 17, drawn to a method for preventing or treating a condition by administering a polypeptide, classified in class 514, subclass 2.
 - V. Claim 18, drawn to a method for preventing or treating a condition by administering a polynucleotide, classified in class 514, subclass 44.
 - VI. Claim 19, drawn to a method of diagnosing a pathological condition by detecting a mutation in a polynucleotide, classified in class 436, subclass 6.
 - VII. Claim 20, drawn to a method of diagnosing a pathological condition by detecting a polypeptide, classified in class 436, subclass 501.
 - VIII. Claim 21, drawn to identifying a binding partner to a polypeptide, classified in class 435, subclass 7.1, for example.

Art Unit: 1646

IX. Claim 23, drawn to a method of identifying an unknown activity in a biological assay, class undeterminable, subclass undeterminable.

X. Claim 24, drawn to a product of unspecified constitution, class undeterminable, subclass undeterminable.

3. The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of invention I, the protein of invention II, the antibodies of invention III and the compound of unspecified constitution that is invention X are four structurally and functionally different chemical compounds, each of which can be made and used without the other compound. Independence and distinctness is shown because these compounds lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the proteins can be made by chemical synthesis or recovered from natural sources.

Inventions II and III are also related as product and process of use. The protein that is invention II can be used in a method of producing the antibody that is invention III, but the antibody can also be made using a chemically synthesized peptide fragment.

Art Unit: 1646

Inventions I and each of inventions V, VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides can be used in the method of make the polypeptides of invention II, or in the method of gene therapy of invention V, or in a method of diagnosis by screening for mutation as in invention VI, or in a method of identifying a binding partner to a polypeptide by using cells transformed with the polynucleotides, all of which are materially different processes .

Inventions III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used in a method of diagnosing a pathological condition by detecting a polypeptide, or in a method of treating a disease.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the necessity for noncoextensive literature searches, restriction for examination purposes as indicated is proper.

4. A telephone call was made to Michele Wales on Sept. 16, 1999 to request an oral election to the above restriction requirement, but did not result in an election being made.

Art Unit: 1646

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached at (703) 308-4310.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D



Patent Examiner

JOHN ULM
PRIMARY EXAMINER
GROUP 1800